EXHIBIT 10

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The Current State of Pain Management: An Expert Interview With Scott M. Fishman, MD

Interviewer: Paula Moyer

Posted: 3/14/2005

Editor's Note:

One of the oldest and strongest imperatives in medicine is to alleviate pain, and yet the effective treatment of pain faces several challenges in today's healthcare environment, particularly with concerns around addictive medications, such as opioids, and questions about the safety of nonsteroidal anti-inflammatory drugs (NSAIDs) and cyclooxygenase-2 (COX-2) inhibitors. At the 21st Annual Meeting of the American Academy of Pain Medicine (AAPM), Medscape *spoke to Scott M. Fishman, MD (Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, University of California, Davis), about those challenges and the ways that pain specialists are addressing them. Dr. Fishman is the recently installed president of the AAPM.*

Medscape: The stated mission of the AAPM is to promote quality care for patients with pain through research, education, advocacy, and advancement of the specialty of pain medicine. What do you think are the greatest barriers to accomplishing the goals of this mission?

Dr. Fishman: The barriers start with the underrecognition of the public health crisis of undertreated pain and the ongoing fragmentation of medicine in its attempts to meet its responsibilities to treat pain and suffering. The discipline of pain medicine has been practiced as a subspecialty with no appropriate parent specialty, and, as a result, medicine's efforts to deal with this public health crisis of undertreated pain have been fragmented. We are going to need to look at more unified, coherent strategies, just as we did when we recognized that emergency room care was being handled by disparate specialists who came to do their work from the narrow scope of the previous training that they had had, but no one was prepared to take care of the whole patient in the emergency room. We are going to need to reevaluate the discipline of pain medicine. There are great responsibilities when treating pain. Doctors must look at pain not just as a symptom, but also as a disease in its own right. Pain itself becomes a disease when the organ involved with perpetuating the alarm of pain becomes damaged and doesn't shut off, leaving the patient with chronic pain. The number of people suffering from chronic pain is huge, exceeding that of many other chronic diseases into which we've put many more resources.

Medscape: You are a strong advocate of pain medicine becoming a discrete discipline within medical practice. Given the diversity of settings that require a physician to provide pain management -- emergency, intensive care, geriatrics, pediatrics, acute care, and outpatient clinics -- how do you propose accomplishing that goal?

Dr. Fishman: If you look at this week's issue of *Time* , which has a cover story on pain, I'm quoted as saying that there's no way that pain specialists will be able to manage even a sizeable fraction of the pain that's out there in America. Pain is an issue in the way that diabetes was 20 or 30 years ago -- specialists are not going to be able to provide the overall solution for this very common chronic illness. Therefore, it will be up to clinicians on the front line of care to accept their responsibilities, and it will be our responsibility to help them have the tools and the strategies for dealing with patients in pain. This will be a main focus of the AAPM: to reach out to primary care and primary specialists who need to provide pain management services.

Medscape: The recent flurry of US Food and Drug Administration (FDA) activity concerning the use of COX-2 inhibitors has led to a lot of confusion among providers about whether to prescribe these agents. What would be your advice concerning the best use of these painkillers?

Dr. Fishman: The use of medications is always based on a risk-benefit analysis. The more we know about risks and the more we know about benefits, the better we are at determining the balance point. This new information allows us to change the outcome of the analysis but doesn't change the need to do the analysis. These are drugs that may help some people in some situations. They may not be appropriate for the widespread distribution that we previously hoped that they would be available for, but nonetheless, there are many cases in which the benefits will outweigh the risks for patients. With this, it is exceedingly important for physicians to understand that when someone is in pain there is no risk-free option, which includes doing nothing. We often encounter the belief that if we do nothing, then that's the safest position, but in fact, when someone is in pain, doing nothing may have much more risk than giving a medication, such as a COX-2. The exact dimension of the risk, particularly the cardiac risk that is posed by COX-2s, has yet to be determined and is an ongoing debate.

There have been 2 recent cases of physicians who were cited for undertreating pain and charged with elder abuse. One was successfully prosecuted, and the other settled before the court date. In 2 cases, physicians have been sanctioned by medical boards for undertreating pain. Laws have arisen from those cases; the Medical Board of California has been forced to publicly document its criterion process for how it will review cases of undertreated pain. The message is very clear: Doctors who refuse to accept their responsibilities to help their patients manage their pain will be perceived as practicing beneath the standard of care. There is no prescribed or specific treatment that must be delivered, but physicians need to embrace the idea that treating pain and suffering is part of our covenant with our patients.

Medscape: Controversy surrounds both the undertreatment and overtreatment of pain. Overtreatment of pain obviously involves the fear of causing or perpetuating opioid drug dependency. What recommendations can you give to primary care physicians who are reluctant to prescribe opioids, either as adjuncts or primary agents for pain control, because of these fears?

Dr. Fishman: It used to be that when you had a patient with pain and you were worried about giving him or her a drug that may be abusable or may cause addiction, the safest thing to do was nothing, as though doing nothing would have no risks in and of itself. We know that the risks of addiction are there, but they are small and can be managed. The AAPM is going to be at the forefront, educating physicians about the difference between analgesia and the outcomes of addiction, which are really diametrically the opposite, because addiction manifests with dysfunction and good analgesia manifests with improved function. With that said, in the current medical-legal environment, physicians may be at just as much risk, if not more, of being judged as undertreating pain if they are not willing to use some modalities. Many have argued that if we try in our zeal to minimize the risk to avoid drugs that are addictive, we often wind up using drugs that may be even more toxic, such as NSAIDs or potentially, in some patients, COX-2 inhibitors. The key is that physicians are always risk managers, and we must do everything in our power to allow the public, the regulators, and law enforcement organizations to understand our responsibility to manage risk and not to interpret that risk management as risk-taking.

Medscape: Schedules II and III are receiving a great amount of scrutiny by the FDA, drug enforcement agencies, and others, and because of physicians' fears of being charged with overprescribing, patients may not be receiving adequate treatment. Is there a solution for this?

Dr. Fishman: The solution is to be careful not to put barriers in front of one schedule or another, because the data are very clear that when physicians are presented with an obstacle in front of one schedule, they prescribe around other schedules. For example, for years triplicates [3-part paper serialized prescriptions] in California suggested to physicians that they should not prescribe schedule II drugs, and because of that we had a very low *OxyContin* abuse rate. However, we had one of the country's most prevalent *Vicodin* abuse problems because people prescribed around the schedule IIs and inappropriately prescribed excessive amounts of schedule IIIs. In California, less than half of physicians even had triplicate prescriptions. There are very good data from New York State showing that when barriers are put in front of benzodiazepines and other drugs, doctors not only go around the barrier to prescribe but they choose drugs that are not only less optimal but more dangerous. So, it really becomes not just a problem for physicians, but a public health hazard.

MEDSCAPE: At this meeting, you participated in a debate about the management of breakthrough pain with short-acting opioids. Can you describe some of the key points in that debate?

Dr. Fishman: My learned colleague, Steve Passik, and myself debated over whether we should or shouldn't use short-acting opioids in chronic pain. In general, I think that there is a consensus that when treating chronic pain the idea is to help patients get off the analgesic rollercoaster of having pain, of taking a medicine, of having pain reduced, of the short-acting medicine wearing off, of the patient having pain again, and the cycle renews. We reached a consensus in this debate that using short-acting opioids chronically as the mainstay of opioid analgesia was probably not appropriate, but using small amounts intermittently may be appropriate in some cases. This debate clearly recognizes that there are those who believe that opioid management for chronic pain should only use sustained-release or long-acting opioids, and others who believe that there may be a place for intermittent small amounts of short-acting opioids.

This program was supported by an independent educational grant from Cephalon.

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